DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

August 14, 2014

Benvenue Medical, Inc.
% Ms. Cindy Domecus
Domecus Consulting Services LLC
1171 Barroilhet Drive
Hillsborough, California 94010

Re: K141141
Trade/Device Name: Kiva® VCF Treatment System
Regulation Number: 21 CFR 888.3027
Regulation Name: Polymethylmethacrylate (PMMA) Bone Cement
Regulatory Class: Class II
Product Code: NDN, LOD
Dated: May 16, 2014
Received: May 19, 2014

Dear Ms. Domecus:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, ″Misbranding by reference to premarket notification″ (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director, Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

4. INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K141141

Device Name: Kiva® VCF Treatment System

Indications for Use:

The Kiva VCF Treatment System is indicated for use in the reduction and treatment of spinal fractures in the thoracic and/or lumbar spine from T6-L5. It is intended to be used in combination with the Benvenue Vertebral Augmentation Cement Kit.

Prescription Use ____X___ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

Concurrence of CDRH, Office of Device Evaluation (ODE)

510(K) SUMMARY

510(k) Owner:

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Date Prepared: June 18, 2014

Device Trade Name: Kiva® VCF Treatment System

Common Name: Cement, bone, vertebroplasty

Classification Name: Polymethylmethacrylate (PMMA) Bone Cement (21 CFR 888.3027)

Device Product Code: NDN, LOD

Predicate Device: Kiva® VCF Treatment System, K132817

Device Description:

The Kiva® VCF Treatment System is provided as a sterile, single use, implantable device which may be used in percutaneous procedures for the reduction and treatment of spinal fractures. The device consists of an implant, a deployment system for the implant, and a set of accessory access instruments. The deployment system component is a single-use, non- implantable device that is used to properly position and deliver the implant. It consists of a nitinol Kiva Coil, which is guided through a deployment cannula into the bone via a hand- operated mechanism. The Kiva Implant, made from PEEK Optima with barium sulfate for radiopacity, is guided over the nitinol Kiva Coil. As the Kiva Implant is pushed over the Kiva Coil, it reduces the fracture via height distraction of the vertebral body. Up to 5 loops of implant may be deployed, corresponding with a maximum height of 15mm. Once the Implant is placed into the vertebral body, PMMA bone cement is deployed into the Kiva Implant. The Kiva Implant contains the PMMA bone cement and helps extravasation. A collection of manual surgical orthopedic instrumentation (Class I needles, stylets, cannulas) is used to gain access to the vertebral body at the start of the procedure, then again later for bone cement deployment. Other instruments are optional for the physician and not provided as part of the Kiva® VCF Treatment System including a Bone Drill, a Bone Biopsy Needle and Kiva Pilot.

Statement of Intended Use:

The Kiva® VCF Treatment System is indicated for use in the reduction and treatment of spinal fractures in the thoracic and/or lumbar spine from T6-L5. It is intended to be used in combination with the Benvenue Vertebral Augmentation Cement Kit.

Summary of Similarities and Differences in Technological Characteristics Between Subject and Predicate Devices:

The modified Kiva® VCF Treatment System has no change to the indications or intended use, no change to the materials or methods of manufacturing and no change to the manner in which the user operates the device or the principles of operation. The only difference is that the modified device allows the user to deliver a maximum of 5 loops of the implant as opposed to 4 loops.

The clinical risks for delivering an implant which has a maximum of 5 loops (15mm maximum height) are equivalent to those for a 4 loop implant (12mm height) as demonstrated by bench and deployment performance testing.

Nonclinical Performance Data:

The performance of the original 4 loop system was evaluated in testing per ASTM F2077-11 (Test Methods for Intervertebral Body Fusion Devices) and ASTM F1877-05 (Standard Practice for Characterization of Particles) in both static and dynamic testing for a worst-case scenario of 4 loops of implant with no PMMA cement present.

This testing was repeated for the 5 loop system in the equivalent worst case configuration with all 5 loops of implant and no cement present. The test results confirmed that the 5 loop system met all of the pre-defined criteria. Thus, the modified system met the same biomechanical performance criteria as the original the 4 loop system.

The performance of the delivery system was evaluated to confirm that all required performance specifications are still met with the modification that permits 5 loops of Kiva Implant. The deployment performance was evaluated in a predefined simulated clinical-use protocol using a total of 30 units in which the Kiva Implant was deployed in human cadaveric spines and into a 7.5 PCF urethane foam analogs of osteoporotic bone. The testing results confirmed that the 5 loop system meets all of the pre-defined criteria. Thus, the modified implant met the same deployment performance criteria as the original 4 loop system.

Conclusion:

The nonclinical tests demonstrate that modified device is as safe, as effective and performs as well as the predicate device.